

FDA – Waiver Guidance Update

- Comment Period Closed – end of 2005
- 40 comments
- Broad range of constituencies
- Broad range of ideas

Waiver Guidance Update

- Comments being analyzed
- Guidance being modified
- High priority
- Challenging work

Waiver Guidance Update

- Target – issue Final Draft end of 2006
- Move forward with Proposed Rule

OIVD

- Busy
- TPLC like
- Established culture
- Still experiencing regulatory growth

Routine Work

- CDC PCR assay for Influenza A/H5
- Series of recalls involving units of measure problems on glucose meters
- Publication of notice of informed consent paper work reduction